



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,532	02/09/2001	Clive Wood	GNN-012CP	8383

Ivor R. Elrifi
MINTZ LEVIN COHEN COHN FERRIS GLOVSKY AND POPEO PC
One Financial Center
Boston, MA 02111

7590 02/12/2008

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
----------	--------------

1636

MAIL DATE	DELIVERY MODE
-----------	---------------

02/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/780,532

Applicant(s)

WOOD ET AL.

Examiner

CELINE X. QIAN

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,7,8,39-43,45-57 and 59-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,7,8,39-43,45-57 and 59-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Art Unit: 1636

DETAILED ACTION

Claims 2, 3, 5, 7, 8, 39-43, 45-57, 59-68 are pending in the application.

This Office Action is in response to the Amendment filed on 11/5/07.

Response to Amendment

The rejection of claims 2, 3, 5-8, 3943, 45-52, 66 and 67 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of the amendment.

The rejection of claims 2, 3, 5, 7, 8, 39-43, 45-57 and 59-68 under 35 U.S.C.112 1st paragraph is maintained for reasons set forth of the record mailed on 5/3/07 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 5, 7, 8, 39-43, 45-57, 59-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 3, 5, 7, 8, 39-43, 45-57, 59-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

Art Unit: 1636

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the new matter rejection, Applicants argue that the support for the amended claims may be found in original claims 15, 16, 18-20 and 25.

This argument is found not persuasive. Original claims 15 and 16 recite a method of modulating the proliferation of a cell comprising contacting the cell with an agent that modulates the expression or activity of a TRADE family member polypeptide, whereas claims 18-20 and 25 recite the agent may be a soluble form of a TRADE family polypeptide comprising a TRADE extracellular domain, wherein the activity is activation of a JNK signaling pathway, NFkB signaling pathway, and activation of apoptosis. As discussed in the previous office action, the instant claims recite "contacting a cell having TRADE activity with a soluble form of a TRADE polypeptide." However, the original claims 15, 16, 18-20 and 25 do not support this recitation because the method of modulating the proliferation of a cell by contacting the cell with an agent that either modulates the expression or activity a TRADE family polypeptide (as claimed in claim 15 and 16) does not require the cell to possess TRADE activity. And this limitation does not have support from the instant specification elsewhere either. Therefore, for reasons discussed in the previous office action and above, the new matter rejection is maintained.

Applicants did not separately address the written description rejection and enablement rejection raised in the previous office action. Applicants assert that the amendment that the TRADE peptide must be a soluble form and to require the modulation of NFkB activation results in a modulation of proliferation of the cell overcomes the rejection because soluble form of TRADE polypeptide can be used as TRADE ligand antagonists to TRADE ligand. Applicants

Art Unit: 1636

further assert that this antagonism of TRADE ligand leads to change in activity of the intracellular portion of the TRADE proteins expressed in a cell to which the soluble TRADE is administered to. Applicants assert that Example 4 demonstrate the modulation of the intracellular portion of the TRADE protein will lead to modulation of NFkB activity.

The above arguments have been considered but deemed unpersuasive. The specification on page 49, 15-19 states "use of TRADE fusion proteins may be useful therapeutically for treatment of disorders, as soluble antagonist of the TRADE ligand." However, the specification fails to demonstrate a soluble form of TRADE polypeptide that encoded by a polynucleotide 98% homologous to the polynucleotide encoding 1-168 amino acid of SEQ ID NO:2 that functions as an antagonist of a TRADE ligand, and thereby modulates the NFkB activation in all cell type in vitro or in vivo. Neither example 4 nor any other portion of the specification demonstrates that such a soluble TRADE polypeptide can change the activity of the intracellular portion of the TRADE protein. While Figure 14 and Example 11 describes the effect of a number of TRADE deletion mutant on the activation of NFkB signaling, it does not show that a soluble polypeptide encoded by a polynucleotide at least 98% to the polynucleotide encoding 1-168 of SEQ ID NO:2 affects or antagonizes the TRADE ligand activation of NFkB signaling pathway because transfection of pcDNA3 and TRADE1-198 has similar effect on the reporter assay. Therefore, for reasons given in the previous office actions and above, the written description rejection and enablement rejection are maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Primary Examiner
Art Unit 1636

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636